REMARKS/ARGUMENTS

Applicant respectfully requests reconsideration of the above-identified application in view of the following remarks.

Claims 1, 2, 5-7, 10-13, 20, 21, 24-26, and 33-39 remain in this application. Claims 36, 38, and 39 have been amended to correct typographical errors therein. All other claims remain unchanged.

Rejections 35 USC § 103

Claims 1, 2, 5-7, 10, 11, 20, 21, 24, 25, 33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang et al. (US 5,559,041) in view of Catt et al. (US 6,451,619) further in view of Yu (US 6,723,500). Claims 1, 2, 5-7, 10, 11, 20, 21, 24, 25, 33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang et al. (US 5,559,041) in view of Catt et al. (US 6,451,619) further in view of Segal et al. (US 6,300,141). Claims 12, 13, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang et al. (US 5,559,041) in view of Catt et al. (US 6,451,619) further in view of Segal et al. (US 6,300,141), as applied to claims 6 and 20, and Freitag et al. (US 6,214,629). Claims 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang et al. (US 5,559,041) in view of Catt et al. (US 6,451,619) further in view of Yu (US 6,723,500), as applied to claims 1, 6, and 20, and Deng (US 6,740,293). Claims 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang et al. (US 5,559,041) in view of Catt et al. (US 6,451,619) further in view of Segal et al. (US 6,300,141), as applied to claims 1, 6, and 20, and Deng (US 6,740,293). The Applicant disagrees with the Examiner.

The presently claimed invention is directed to a platform that has a sample application means and having top and bottom layers with hydrophilic surfaces to enclose and position a membrane(s). Each layer having a top and bottom layer surface formed so that the bottom surface of the top layer and the top surface of the bottom layer may be brought into fixed face to face contact so that the layers enclose and hold the membrane in place and form a platform flow channel upstream of the membrane and including at least one indent in at least one of the hydrophilic surfaces. The formed channel is in fluid communication with the membrane to permit the liquid sample to flow in a continuous pathway from the sample

application means to the distal end of the membrane. In this claimed arrangement, the sample is provided at one end into the platform flow channel. This is upstream of the membrane. The liquid flows to the membrane and therethrough.

In contrast, in all of the cited references, the devices are constructed such that sample is applied directly on a top portion of the membrane and then flows through. This requires a large sample volume that spreads right into one end of the membrane and then flows for a reaction to occur. In the claimed invention, only a small sample is required and is applied laterally and flows laterally through the platform flow channel before it actually reaches the membrane.

The Examiner submits that Kang et al. fail to teach the platform formed by face to face contact of a top and bottom layer having a bottom and top hydrophilic surface, respectively and an indent in a least one of the hydrophilic surfaces. The Examiner also alleges that the aperture of Kang et al. is equivalent to the presently claimed sample application means. The Applicant disagrees and asserts that Kang et al. fail to teach a platform flow channel upstream of the membranes. The aperture of Kang et al. is not upstream of the membranes. Instead, it is situated directly over the reservoir pad (col. 4, line 52).

Furthermore, Kang et al. fail to teach that the liquid sample flows in a continuous pathway from the sample application means to the distal end of the membranes. In the presently claimed invention, the sample is applied to the sample application means and the sample flows continuously therefrom. In contrast, Kang et al. teach that the sample is applied to the sample application means (the aperture) on top of the reservoir pad. Gravity forces the sample down onto the reservoir pad where it is absorbed (i.e. the sample diffuses out in all directions; col. 4, lines 57-58).

In addition, it is taught that the reservoir pad of Kang et al. can hold a large quantity of sample (col. 6, lines 18-19). Therefore, the device of Kang et al. is not suitable for use with a low volume liquid sample as presently claimed. In the many examples disclosed by Kang et al., the minimum volume of sample used is 100 µl. Even in Examples 14 and 15, where microliters of serum and 10 µl of sample are used, respectively, it is taught that there is a need to add a further 100 µl of a test suspension. In contrast, the presently claimed device is useful with low volume liquid samples, such as one or a few drops of whole blood, from about 10 µl to about 50 µl (paragraph 22).

Therefore, the teachings of Kang et al. are not only deficient with respect to the platform being formed by face to face contact of a top and bottom layer having a bottom and top hydrophilic surface, respectively and an indent in a least one of the hydrophilic surfaces, they are also deficient with respect to the presence of a platform flow channel upstream of the membranes, the liquid sample flowing in a continuous pathway from the sample application means to the distal end of the membranes, and use with a low volume liquid sample as presently claimed.

The teachings of Catt et al. do not overcome the deficiencies of Kang et al. Although Catt et al. teach top and bottom layers in face to face contact, they do not teach that these form a platform flow channel upstream of the membranes. Instead, the indent taught by Catt et al. is contiguous with the membranes, rather than upstream of the membranes. As the Examiner states, "102 is indented to hold the membrane, 202". In the presently claimed device, the indent forming the platform flow channel does not hold the membrane, it accepts the sample and is upstream of the membranes. Furthermore, like Kang et al., Catt et al. also fail to teach the liquid sample flowing in a continuous pathway from the sample application means to the distal end of the membranes, and use with a low volume liquid sample as presently claimed. The Examiner also submits that Catt et al. fail to teach that the plastic platform is hydrophilic.

The teachings of Yu do not overcome the deficiencies of Kang et al. and Catt et al. Specifically, Yu fails to teach the presence of a platform flow channel upstream of the membranes, and the liquid sample flowing in a continuous pathway from the sample application means to the distal end of the membranes, as presently claimed. Furthermore, the Applicant points out that Yu teaches that the channel within the membrane (and optionally the bottom layer of the membrane) is hydrophilic, and is silent with respect to the platform itself having top and bottom layers with hydrophilic surfaces, as presently claimed.

The teachings of Segal et al. also do not overcome the deficiencies of Kang et al. and Catt et al. Like Yu, Segal et al. teach that the membrane is made of a bibulous (hydrophilic material) and is silent with respect to the platform itself having top and bottom layers with hydrophilic surfaces, as presently claimed.

The teachings of Freitag et al., with respect to reagents for use in the detection of Troponin I in a blood sample, fail to overcome the deficiencies of Kang et al., Catt et al. and Segal et al. Similary, the teachings of Deng, with respect to cylindrical pillars that register with indents and open areas that inhibit flow of sample between the top and bottom layers, also fail to overcome the deficiencies of Kang et al., Catt et al. and Yu or Segal et al.

The Applicant asserts that none of the above-identified cited references teach or suggest the presence of a platform flow channel upstream of the membranes as presently claimed. The presence of the platform flow channel upstream of the membranes provides the presently claimed invention with several surprising advantages. First, it serves as a built-in sample volume control mechanism. Due to the various capillary forces involved in the presently claimed device, the diagnostic reaction will only begin if enough blood is received in the sample flow channel (paragraph 43). Furthermore, the platform flow channel provides for the sample to enter the membrane laterally from one edge. In contrast, in the cited references, sample is applied to the top surface of the membranes. The presently claimed invention therefore reduces wasted sample that flows contrary to the direction of the main flow (paragraph 36). As described above, none of the cited references teach or suggest a platform itself having top and bottom layers with hydrophilic surfaces or a liquid sample flowing in a continuous pathway from the sample application means to the distal end of the membranes. None of the cited references alone or in combination provide the claimed recited features and also don't teach the advantages of the presently claimed invention. Therefore, it is respectfully requested that the Examiner's rejections be withdrawn.

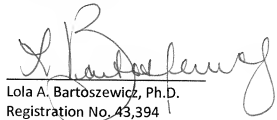
Conclusion

The Applicant requests the Examiner reconsider and withdraw all outstanding objections and rejections, enter the amendments, and pass the resulting claims to allowance.

Should the examiner wish to discuss the application, a telephone call to the undersigned attorney would be welcome.

Respectfully Submitted,

SIM & McBURNEY



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